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Application No.	:	**2,439,303**
Owner	:	PRAECIS PHARMACEUTICALS INCORPORATED
Title	:	**METHODS FOR IDENTIFYING PEPTIDES WHICH MODULATE A BIOLOGICAL PROCESS**
Classification	:	C12Q-1/00
Your File No.	:	**PAT 55379W-1**
Examiner	:	Nicole Harris

YOU ARE HEREBY NOTIFIED OF :

- A REQUISITION BY THE EXAMINER IN ACCORDANCE WITH SUBSECTION 30(2) OF THE *PATENT RULES*;
- A REQUISITION BY THE EXAMINER IN ACCORDANCE WITH SECTION 29 OF THE *PATENT RULES*.

IN ORDER TO AVOID **MULTIPLE ABANDONMENTS** UNDER PARAGRAPH 73(1)(A) OF THE *PATENT ACT*, A WRITTEN REPLY **TO EACH REQUISITION** MUST BE RECEIVED WITHIN 6 MONTHS AFTER THE ABOVE DATE.

This application has been examined as originally filed.

The number of claims in this application is 63.

A search of the prior art has revealed the following:

Mol Cell Biochem. 1997 Jul;172(1-2):67-79. Gietz et al.

Gietz et al. disclose a yeast system for screening cDNA libraries to identify proteins, and corresponding encoding cDNAs, that have a biologically significant interaction with a specified protein in the yeast.

The examiner has identified the following defects in the application:

Claims 31, 46 and 63 do not comply with Paragraph 28.2(1)(b) of the Patent Act. Gietz et al. disclosed the claimed subject matter before the claim date. These claims use such broad and general language that they encompass the yeast two-hybrid screening methods of Gietz et al.

Claims 1-9, 13-45 and 47-56 do not comply with Section 28.3 of the *Patent Act*. The subject matter of these claims would have been obvious on the claim date to a person skilled in the art or science to which they pertain. The instant application merely recites accepted methodologies for producing and screening a peptide or peptide expression library without giving specific direction for producing a specific library for use in an unobvious screening method (Sambrook et al., on page 7).

Claims 58 do not comply with Section 28.3 of the *Patent Act*. The subject matter of these claims would have been obvious on the claim date to a person skilled in the art or science to which they pertain having regards to Gietz et al. It would be obvious to someone skilled in the art to further investigate biologically significant peptides, identified in a library screening method, molecular modeling and recombinant DNA technology.

Claim 1 is indefinite and does not comply with Subsection 27(4) of the Patent Act. This claim is directed towards a method and therefore requires that detailed steps and reagents necessary to carry out said method be included in the claim. Specifically, the claim needs to define the biological process being investigated and how the modulation of said biological process is assessed.

Claims 1 and 25-27 are indefinite and do not comply with Subsection 27(4) of the Patent Act. The description defines "organism" to include mammals (page 5 and 13). It is unclear how mammals can be "contacted" with a peptide library as outlined in step a). Further, if said method includes mammals the method would be considered a method of medical treatment and outside the definition of invention according to Section 2 of the Patent Act.

Claims 1 and 25-28 are broader in scope than the teaching of the description. Though the method for identifying peptides which modulate biological processes may be apparent to someone skilled in the art, such general terminology would encompass all possible combinations of biological processes, organisms, cells, tissues and peptide libraries which falls outside the scope of the instant application. To comply with Section 84 of the Patent Rules these claims must be limited to mammalian cells used to screen human or viral libraries for modulators of defined biological processes.

Claim 8 is indefinite and does not comply with Subsection 27(4) of the Patent Act. The disease state is not defined in distinct and explicit terms.

Claim 29 is ambiguous and does not comply with Subsection 27(4) of the Patent Act. It is unclear where the "additional amino acid sequences" are attached to the peptides of the library.

Claim 30 is indefinite and does not comply with Subsection 27(4) of the Patent Act. This claim is directed towards a method which therefore requires that detailed steps and reagents necessary for carrying out said method be included in said claim. "Forming" fails to define the steps necessary for producing a second library. "Selecting" fails to define how peptides that modulate the biological process are chosen. Further, "designed" is directed towards a desired result and "non-peptide compound" fails to define the structure of said compound.

Claim 31 is indefinite and does not comply with Subsection 27(4) of the Patent Act. This claim is directed towards a method and therefore requires that detailed steps and reagents necessary to carry out said method be included in the claim. Specifically, the claim needs to define the biological process being investigated, how a cell in which the biological process is modulated is selected and how the nucleic acid sequence of the peptides are determined.

Claim 31 is indefinite and does not comply with Subsection 27(4) of the Patent Act. The term "the genome" has no antecedent.

Claims 34-40 and 52-55 are ambiguous and do not comply with Subsection 27(4) of the Patent Act. The phrase "the peptide library comprises fragments of x or more proteins encoded by the genome of an organism" fails to specifically define the peptide libraries of these claims since the process of generating the expression vectors for said libraries would inherently contain fragments of proteins encoded by the genome of the organism.

Claim 39 is indefinite and does not comply with Subsection 27(4) of the Patent Act. This claim needs to end with a period.

Claim 46 is indefinite and does not comply with Subsection 27(4) of the Patent Act. This claim is directed towards a method and therefore requires that detailed steps and reagents necessary to carry out said method be included in said claim. Specifically, the claim needs to define how a cell in which infectivity is modulated is selected and how the nucleic acid sequence of the peptides are determined.

Claim 57 is outside the definition of invention in Section 2 of the Patent Act. An allegedly new method of identifying peptides does not bestow patentability on old and known peptides.

Claim 58 is indefinite and does not comply with Subsection 27(4) of the Patent Act. The term "the molecular modeling" has no antecedent.

Claim 58 is outside the definition of invention in Section 2 of the Patent Act. An allegedly new method of identifying peptides does not bestow patentability on a known use of old and known peptides.

Claim 59 is outside the definition of invention in Section 2 of the Patent Act. An allegedly new method of identifying peptides does not bestow patentability on pharmaceutical compositions containing old and known peptides .

Claims 60-62 are directed to a method of medical treatment which is outside the definition of invention in Section 2 of the Patent Act. (See Tennessee Eastman v Commissioner of Patents (1974) S.C.R. 111).

Claim 60 is indefinite and does not comply with Subsection 27(4) of the Patent Act. The "disease", "condition associated with an aberrant biological process" and "peptide" are not defined in distinct and explicit terms.

Claims 60-63 does not comply with Section 84 of the Patent Rules. The instant application is directed towards a method for determining peptides that alter biological processes. Since specific biological processes and specific peptides that modulate said processes have not been identified it is problematic to conclude that said peptides would have the predicted utility of treating specific diseases or conditions (Apotex Inc. v. Wellcome Foundation Ltd., 2002 SCC 77).

Claim 63 is outside the definition of invention in Section 2 of the Patent Act. A kit must comprise novel components or name specific novel combinations of components which cooperate for a novel use.

This application does not comply with Subsection 27(3) of the Patent Act. The specification does not correctly and fully describe the invention and its operation or use. The instant application only recites general methodologies for producing and screening peptide and peptide expression libraries and fails to provide any specific methodology for producing and screening the preferred type of "peptide library" or "nested peptide library" disclosed on page 7 of the description. Further, the examples in the application only define the construction of a vector system into which the library can be cloned and an unobvious screening method for a library using cultured cells.

A statement in an application, such as found on page 1, line 6, page 11, lines 2 and 35, page 17, line 16, page 20, line 35 and page 21, lines 5, 10 and 25 which incorporates by reference any other document, does not comply with Subsection 81(1) of the Patent Rules.

In accordance with Subsection 81(2) of the Patent Rules, all documents referred to in the description of an application must be available to the public. Reference to the document on page 1, line 5 must be deleted or replaced by its corresponding patent or publication number.

In accordance with Subsection 81(2) of the Patent Rules, all documents referred to in the description of an application must be available to the public. Reference to the hyperlinks found in the table on page 13 are not acceptable references since the links are not static and may change over time. These references must be refer to the source of the hyperlink or corresponding document.

In view of the foregoing defects, the applicant is requisitioned, under Subsection 30(2) of the Patent Rules, to amend the application in order to comply with the Patent Act and the Patent Rules or to provide arguments as to why the application does comply.

Under Section 29 of the *Patent Rules*, applicant is requisitioned to provide an identification of any prior art cited in respect of the United States and European Patent Office applications describing the same invention on behalf of the applicant, or on behalf of any other person claiming under an inventor named in the present application, and the patent numbers, if granted, subsequent to the International Search Report.

In order to assist the prosecution of this application, applicant is requisitioned to provide a copy of all non-patent documents cited during the prosecution by the United States and European Patent Offices, under Section 29 of the *Patent Rules*. In accordance with Subsection 29(3) of the *Patent Rules*, if at least one of the documents is not available to the applicant, the reason must be stated.

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